JUL 1 2003

ADMINISTRATIVE INFORMATION

Manufacturer Name:
MacroPore Biosurgery, Inc.
6740 Top Gun Street
San Diego, CA 92121

Official Contact:
Kenneth K. Kleinhenz
Director of Regulatory Affairs
Telephone (858) 458-0900
Fax (858) 458-0994

DEVICE NAME

Classification Name: Plate, Fixation, Bone
Trade/Proprietary Name: MacroPore OS Reconstruction System

ESTABLISHMENT REGISTRATION NUMBER

2031733

DEVICE CLASSIFICATION AND PRODUCT CODE

As shown in 21CFR 888.3030 bone fixation appliances intended for use in orthopedic procedures are classified as Class II. They have been assigned Product Code HRS.

INTENDED USE

The MacroPore OS Reconstruction System is intended to maintain the relative position of weak bony tissue such as bone grafts, bone graft substitutes, or bone fragments from comminuted fractures. The flat Protective Sheets with pore sizes up to 2.5mm are also indicated for cement restriction in total joint arthroplasty procedures.

Only when used in conjunction with traditional rigid fixation, the MacroPore OS Reconstruction System is intended to maintain the relative position of weak bony tissue in trauma and reconstructive orthopedic procedures involving:

- Long bones
- Flat bones
- Short bones
- Irregular bones
- Appendicular skeleton
- Thorax

When used alone (without traditional rigid fixation), the MacroPore OS Reconstruction System is intended to maintain the relative position of bone grafts or bone graft substitutes in reconstructive orthopedic procedures involving:

- Tumor resections where bone strength has not been compromised
- Iliac crest harvests
- Ribs (excluding multiple segmental defects such as those found in flail chest)

This device is not intended for use in the spine. The device is not intended for load bearing indications unless used in conjunction with traditional rigid fixation.

Design Characteristics

MacroPore OS Reconstruction System is a resorbable graft containment system composed of various sized porous sheet and sleeves, non-porous sheets and sleeves, and associated fixation screws and tacks manufactured from polylactic acid (PLA). The MacroPore OS Reconstruction System is composed of MacroPore OS Reconstruction System Protective Sheets, MacroPore OS Reconstruction System Protective Sleeves, and MacroPore OS Reconstruction Screws and Tacks.

The MacroPore OS Reconstruction System Protective Sheets and Protective Sleeves can be cut with scissors to the desired shape and size. The MacroPore Power Pen can also be used to cut or shape the MacroPore OS Reconstruction System to the desired shape or size. MacroPore OS Reconstruction System Protective Sheets and Protective Sleeves are fully malleable when heated to approximately 55°C (for example, by the use of sterile hot water), and thus can be conformed three dimensionally to most any anatomical orientation.

The MacroPore OS Reconstruction System Protective Sheets can be rolled into a tube or used as a flat sheet. The MacroPore OS Reconstruction System Protective Sheets and Protective Sleeves can be used either alone or in conjunction with internal bone fixation devices such as plates and screws, which also can serve to fixate the MacroPore OS Reconstruction System and prevent dislocation.

The MacroPore OS Reconstruction System Tacks range in size from 1.7mm to 2.2mm in diameter with lengths from 3.6mm to 5.6mm and the MacroPore OS Reconstruction System Screws range in size from 2.0mm to 4.75mm in diameter with lengths from 3.35mm to 30mm. The MacroPore OS Reconstruction System Protective Sheet is provided in sheets of 25 x 25 mm to 160 x 200 mm. The MacroPore OS Reconstruction System Protective Sleeves are provided in lengths of 150mm to 5mm with inner diameter diameters that range from 5mm up to 40mm. The MacroPore Reconstruction System Protective Sleeves are provided in circular, rectangular, square, trapezoidal, and parabolic shapes. The MacroPore OS Reconstruction System Protective Sleeves are provided with and without serrated edges and / or tapered end(s) for ease of surgical installation. The MacroPore OS Reconstruction System Protective Sheets and Protective Sleeves are provided with and without macroporous holes. The pore size ranges from 1.7mm to 4.0mm in diameter, with pores distributed randomly or uniformly throughout the sheet/sleeve in an offset or aligned pattern. The thickness of the MacroPore OS Reconstruction System Protective Sheets ranges from 0.5mm to 5.0mm according to the orthopedic region to be treated. The thickness of the MacroPore OS Reconstruction System Protective Sleeves ranges from 0.8mm to 5.0mm according to the orthopedic region to be treated.

Material Composition

The MacroPore OS Reconstruction System is fabricated from polylactic acid (PLA).

In Vitro Testing

Because the MacroPore OS Reconstruction System Protective Sheet is intended to be heated in the surgical suite to temperatures above the material's glass transition temperature to facilitate shaping to anatomic structures, testing was performed to determine the effect of prolonged heating in saline at 60°C on inherent viscosity. The testing demonstrates that viscosity stayed within an appropriate range over 120 minutes. Therefore, the relatively brief exposure anticipated during the surgical preparation of MacroPore OS Protective Sheet is not expected to have a significant effect on its mechanical properties.

Aging studies were performed on MacroPore OS Reconstruction System components. Testing demonstrated that the MacroPore OS Reconstruction System Protective Sheet is as rigid and as strong as the predicate after 6 months of exposure. Mechanical testing was performed on the MacroPore OS Reconstruction System Protective Sheets and MacroPore OS Reconstruction System Screws. Testing determined the MacroPore OS Reconstruction System to be substantially equivalent to the mechanical strengths of the predicate devices under indication for use conditions.

Crystallinity was tested for by DSC (differential scanning calorimetery). This test measures the amount of heat energy that is absorbed by a material. A crystalline material will require more energy once it reaches it's melting point. This release of heat energy can be seen on a graph as a sharp spike and is referred to as a "melting endotherm". The tests ran on the sterile and non-sterile samples revealed no endothermic spikes, indicating that the implants are amorphous and non-crystalline.

EQUIVALENCE TO MARKETED PRODUCT

The MacroPore OS Reconstruction System shares materials, indications, and design principles with the following predicate devices which have been determined by FDA to be substantially equivalent to pre-amendment devices: MacroPore OS Protective Sheet and Synthes Resorbable Meshes and Sheets.

Indications For Use

The MacroPore OS Reconstruction System shares substantially equivalent indications for use with the predicate devices.

Design and Materials

The design and materials of MacroPore OS Reconstruction System and the predicate devices (MacroPore OS and Synthes Resorbable Sheet) are nearly identical as they all are made from resorbable polylactide (PLA) material and are provided in sheets and have fixation screws and tacks of similar shapes and sizes. Both the predicate device and the MacroPore OS Reconstruction System Sheet have a semi-rigid construction with pores of similar diameter and spacing. The pore size and spacing of the predicate device is within the pore size and spacing specifications of the MacroPore OS Reconstruction System Protective Sheets. The dimensions of the predicate device are also comparable to the MacroPore OS Reconstruction System sheet as both devices are provided in rectangular sheets that are several centimeters in size. The mechanical characteristics of the MacroPore OS Reconstruction System are substantially equivalent to the predicate device with respect to tensile strength, shear strength, and rigidity as measured by the materials spring constant. In addition to physical characteristics, both the predicate device and the MacroPore OS Reconstruction System Sheets can be shaped with warm water and cut to specific shapes and sizes by the end user.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 2003

Mr. Kenneth K. Kleinhenz
Director of Regulatory Affairs
MacroPore Biosurgery, Inc.
6740 Top Gun Street
San Diego, California 92121

Re: K024169
Trade/Device Name: MacroPore OS Reconstruction System
Regulation Number: 21 CFR 878.3300, 888.3030, 888.3040
Regulation Name: Surgical mesh, Single/multiple component metallic bone fixation appliances and accessories, Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: EZX, HRS, HWC, and MAI
Dated: April 4, 2003
Received: April 7, 2003

Dear Mr. Kleinhenz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

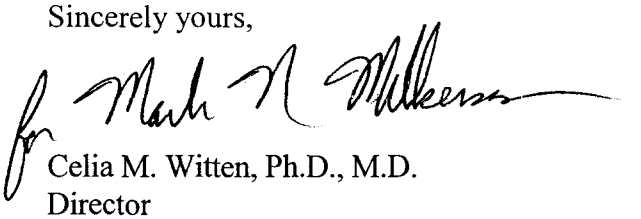
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K024169

Device Name: **MacroPore OS Reconstruction System**

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use _____

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K024169